

detect such analyte(s). In particular, the instant claims relate to apparatuses and kits that use an assay control for measuring the progress and time of completion of an assay.

Claims 27-28 and 93-108 are pending in the instant application, with claims 6-7, 16-17, 29-47 and 54-92 having been cancelled by Applicants. Applicants respectfully request reconsideration of the present application in view of the following comments.

*Non-Art Related Remarks*

Finality of the office action

In Paper No. 13, paragraph 12(II), the Examiner has withdrawn the rejection of claims 29, 93, 94, and 96-100 under 35 U.S.C. §103(a), alleging that the claims are unpatentable over Buechler *et al.*, U.S. Patent No. 5,458,852 in view of Van Deusen *et al.*, US Patent No. 5,132,097. In Paper No. 13, paragraph 14(I), the Examiner has rejected the same claims under the same section of 35 U.S.C. §103 over precisely the same combination of references under the heading "new grounds of rejection necessitated by amendment."

In Paper No. 13, paragraph 12(III), the Examiner has withdrawn the rejection of claim 95 under 35 U.S.C. §103(a), alleging that the claims are unpatentable over Sheppard *et al.*, U.S. Patent No. 6,143,247 or Buechler *et al.*, U.S. Patent No. 5,458,852 in view of Van Deusen *et al.*, US Patent No. 5,132,097 in further view of Slovacek *et al.*, U.S. Patent No. 5,424,837. In Paper No. 13, paragraph 14(II), the Examiner has rejected the same claims under the same section of 35 U.S.C. §103 over precisely the same combination of references under the heading "new grounds of rejection necessitated by amendment."

In Paper No. 13, paragraph 12(IV), the Examiner has withdrawn the rejection of claims 28 and 101-108 under 35 U.S.C. §103(a), alleging that the claims are unpatentable over Sheppard *et al.*, U.S. Patent No. 6,143,247 or Buechler *et al.*, U.S. Patent No. 5,458,852 in view of Van Deusen *et al.*, US Patent No. 5,132,097 in further view of Slovacek *et al.*, U.S. Patent No. 5,424,837 and in further view of Zuk *et al.*, U.S. Patent No. 4,281,061. In Paper No. 13,

paragraph 14(III), the Examiner has rejected the same claims under the same section of 35 U.S.C. §103 over precisely the same combination of references under the heading "new grounds of rejection necessitated by amendment."

Applicants address the merits of these rejections below. However, Applicants respectfully request that the Examiner clarify how the rejection may be withdrawn, and yet be a new ground of rejection necessitated by amendment.

Information Disclosure Statement

The Examiner has maintained the objection and requested a new submission of an information disclosure statement. Applicants respectfully traverse the objection, and submit that the Examiner has misinterpreted the Applicants' remarks presented in the response mailed on November 9, 2001.

As noted in MPEP §609(I)(A)(2), an examiner shall consider information which has been considered by the Office in a parent application when examining a continuation application filed under 37 CFR 1.53 (b). Such information need not be resubmitted in the continuing application unless the applicant desires the information to be printed on the patent.

Applicants respectfully submit that this application is a continuation of U.S. Patent Application No. 09/003,065, now U.S. Patent No. 6,194,222B1. All the information listed in the information disclosure statement provided to the Examiner in the instant case was considered in the parent application. Accordingly, as stated in MPEP §609(I)(A)(2), such information need not be resubmitted in the instant continuing application. The unsigned information disclosure statement submitted in the instant application was merely for the Examiner's convenience in identifying the information considered in the parent application, and that should, therefore, be considered by the Examiner in the instant application.

35 U.S.C. §112, Second Paragraph

Applicants respectfully traverse the rejection of Claims 28 and 101-108 under 35 U.S.C. §112, second paragraph, as allegedly being incomplete for omitting essential elements, *i.e.* kit components/reagents. Paper No. 13, page 8.

Applicants respectfully disagree that the rejected claims are “incomplete for omitting essential elements [such as] kit components/reagents, which would include positive elements with respect to [a] kit.” Paper No. 13, paragraph 13. The Examiner is incorrect in asserting that “[i]nstructions are not patentable in a kit” and that “the printed matter on the instructions in a kit cannot serve to define the kit over the prior art.” *Id.* Rather, the case cited by the Examiner in support of these assertions, *In re Gulack*, 703 F.2d 1381 (Fed. Cir. 1983), takes precisely the opposite position from that stated by the Examiner.

For example, on page 1385, the Court of Appeals for the Federal Circuit in *Gulack* states “[d]ifferences between an invention and the prior art cited against it cannot be ignored merely because those differences reside in the content of printed matter... The claim must be read as a whole.” This is emphasized again by the Court of Appeals for the Federal Circuit in *In re Lowry*, 32 F.3d 1579 (1994), in which it is stated “[t]he Patent and Trademark Office (PTO) must consider all claim limitations when determining patentability of an invention over the prior art.... The PTO may not disregard claim limitations comprised of printed matter” (internal citation to *Gulack* omitted, emphasis added). Thus, the Examiner’s assertions in this regard exhibit a lack of understanding of the settled law.

Moreover, whether or not the printed matter in a kit defines a kit over the prior art is not probative as to whether limitations in a claim are incomplete. In order for an element to be essential, the element must be defined by applicants as being necessary to practice the invention. *See, e.g.*, MPEP §2172.01. The Examiner does not indicate that any such limitations are missing from the claims. Instead, the Examiner improperly ignores elements of the claims, and thereby asserts that there are no positive limitations recited in the claims with respect to a kit. Applicants

respectfully submit that this failure by the Examiner to properly consider the rejected claims renders the rejection fatally flawed.

Because claim 28 and its dependent claims 101-108 particularly point out and distinctly claim the subject matter of the instant invention, the requirements of 35 U.S.C. §112, second paragraph, have been met. Applicants, therefore, respectfully request that the rejection be reconsidered and withdrawn.

*Art-Related Remarks*

35 U.S.C. §103(a)

Applicants respectfully traverse the rejection of Claims 27, 93, 94, 96, 97, 98, 99 and 100 under 35 U.S.C. §103(a), as allegedly being unpatentable over Buechler *et al.*, U.S. Patent No. 5,458,852 ("the '852 patent") or Sheppard *et al.*, U.S. Patent No. 6,143,247 ("the '247 patent") in view of Van Deusen *et al.*, US Patent No. 5,132,097 ("the '097 patent").

To establish a *prima facie* case of obviousness, three criteria must be met: there must be some motivation or suggestion, either in the cited references or in knowledge available to the ordinarily skilled artisan, to modify or combine the references; there must be a reasonable expectation of success in combining the references; and the references must teach or suggest all of the claim limitations. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991) See also MPEP §2143.

*The instant claims*

The instant claims refer to devices configured to comprise a diagnostic lane having at least one zone configured to bind an analyte of interest, and at least one timing zone. The devices further comprise an optical component for detecting a signal from the timing zone. Finally, the devices further comprise a signal processor configured to determine the progress and time of completion of an assay for the analyte of interest from the timing zone signal.

*The '852 patent*

With regard to the '852 patent, the Examiner contends that "[a]lthough the reference is silent with respect to the intended use of the apparatus (measuring progress and time of completion for an assay), the claimed functional limitation would be inherent [sic] property of the referenced device." Paper No. 13, page 9. The Examiner, however, cites no support in the '852 patent for this assertion. The mere fact that such a characteristic may occur is not sufficient to establish inherency. Rather, the Examiner must establish that the characteristic(s) in question must necessarily be provided by the cited publication. *See, e.g.,* MPEP §2112.

As described in the instant specification, the phrase "timing zone" refers to a zone in (which the signal obtained from the zone is related to the flow of reagents through the device) but is not related to the presence or amount of the analyte of interest in the assay. For example, in the exemplary embodiment on pages 69-70, the specification describes an assay device comprising a diagnostic lane with several analyte-specific detection zones that bind labeled species in an analyte-specific manner, and a timing zone that does not specifically bind any of the labeled species used in these analyte assays. The signal obtained from the timing zone is related to the amount of labeled species free in solution and the amount of labeled species that might nonspecifically bind at the timing zone. As the fluid begins to traverse the diagnostic lane, fluorescence observed from the timing zone is high, as the concentration of labeled species present in the assay fluid is high. Completion of the assay is signalled by a loss of fluorescence in the timing zone, indicating that the unbound labeled species within the device have now exited the diagnostic lane.

*free in the  
Spec.*

It is not suggested by the Examiner that the '852 patent discloses configuring a device to comprise such a timing zone, an optical component to detect a signal from such a timing zone, or a signal processor to determine the progress and time of completion of an assay for the analyte of interest from the timing zone signal. Rather, the Examiner simply asserts, without support, that measuring progress and time of completion for an assay would be inherent to the devices of the '852 patent. Applicants respectfully request that the Examiner provide extrinsic evidence making

it clear that each limitation of the instant claims is necessarily provided by the devices disclosed in the '852 patent.

*The '247 patent*

Similarly, with regard to the '247 patent, the Examiner again contends that "[a]lthough the reference is silent with respect to the intended use of the apparatus (measuring progress and time of completion for an assay), the claimed functional limitation would be inherent [sic] property of the referenced device." Paper No. 13, page 10. Again, the Examiner, however, cites no support in the '247 patent for this assertion. Applicants respectfully request that the Examiner provide extrinsic evidence making it clear that each limitation of the instant claims is necessarily provided by the devices disclosed in the '247 patent.

*unintended  
use!*

Moreover, the Examiner contends that the '247 patent contains a signal processor, referring to a "detector or optical heads." Paper No. 13, page 10. Applicants respectfully submit that nothing of record indicates that these elements described in the '247 patent perform any signal processing function, much less that these elements are configured to receive an electronic signal from an optical component and to determine the progress and time of completion of an assay, as recited in the instant claims.

*individual  
analyses*

*The '097 patent*

Furthermore, contradicting the assertion that measuring progress and time of completion for an assay would somehow be inherent in the devices of the '852 and '247 patents, the Examiner states that, while these patents do not disclose "an optical component and a signal specifically configured to generate and read electronic signals,... it would have been obvious to one of ordinary skill in the art... to measure optical signals via a signal processor as taught by [the '097 patent]." The asserted motivation for this combination is "to greatly reduce the time required for analysis."

Whether or not it is true that the '097 patent discloses any such elements, Applicants respectfully submit that the Examiner has ignored the fact that nothing in the patents cited by the Examiner discloses or suggests that a timing zone should be provided in a device, that an optical component should be configured to read a signal from such a timing zone, or that a signal processor should be configured to determine the progress and time of completion of an assay for an analyte of interest from the timing zone signal. \*

Thus, even if the cited patents are combined as suggested by the Examiner, the asserted combination fails to teach or suggest each and every element of the instantly claimed invention. Furthermore, no publications of record in the instant rejection provides any motivation to modify the devices in the cited publications to provide each and every element of the instant claims. Therefore, because no *prima facie* case of obviousness has been established, Applicants respectfully request that the rejection under 25 U.S.C. §103 be reconsidered and withdrawn.

The Examiner has also rejected claim 95 under 35 U.S.C. §103(a) as allegedly being unpatentable over Sheppard *et al.* or Buechler, in view of Van Deusen *et al.*, in further view of Slovacek *et al.*, U.S. Patent No. 5,424,837 ("the '837 patent"); and claims 28 and 101-108 in further view of Zuk *et al.*, U.S. Patent No. 4,281,061 ("the '061 patent"). Applicants respectfully traverse these rejections.

For the reasons discussed above, the cited Sheppard *et al.*, Buechler, and Van Deusen *et al.* patents, alone or in combination, do not teach or suggest every claim limitation. The '837 and '061 patents do not cure the flaws in the Examiner's asserted obviousness rejection, nor is it contended that they do so. Therefore, no *prima facie* case of obviousness has been established. Applicants, therefore, respectfully request that the rejection under 35 U.S.C. §103(a) be reconsidered and withdrawn.

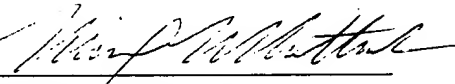
### CONCLUSION

In view of the above remarks, Applicants believe that the present application is now in condition for allowance. Reconsideration and favorable action on all claims, and allowance of the

claims are respectfully requested. In the event any matters remain to be resolved in view of this communication, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

Respectfully submitted

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